

Appl. No. 10/078,042
Docket No. 8430
Amdt. dated August 8, 2007
Reply to Office Action mailed on May 21, 2007
Customer No. 27752

REMARKS

Claim Status

Claims 1 – 10 are pending in the present application. No additional claims fee is believed to be due.

Claim 8 has been amended to include the feature of a data acquisition mechanism being adapted to perform a preliminary analysis on data and provide an output when the data comprises a value that is outside of a control limit. Support for this amendment can found at page 15, lines 18 – 21 of the Specification.

Claim 8 has also been amended to include the feature of a data analysis mechanism being adapted to generate information that includes at least one level of intervention when the data comprises a value that is outside of a control limit. Support for this amendment can be found at page 16, lines 1 – 5 of the Specification.

Claim 9 has been amended to correct grammatical errors.

It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §103(a) Over Sheehan in View of Frasca, Jr.

Claims 1 – 2, and 5 – 10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 6,319,199 to Sheehan, *et al.*, (hereinafter “Sheehan”) in view of U.S. Pat. No. 6,055,506 to Frasca Jr., *et al.*, (hereinafter “Frasca”). Applicants respectfully traverse the rejection.

The Office Action asserts that Sheehan discloses “a data acquisition mechanism transferring the data relevant to a particular health condition from the data measurement mechanism to a storage medium.” (The Office Action, page 2). However, claim 8 recites, *inter alia*, a data acquisition mechanism being adapted to perform a preliminary analysis on the data and provide an output when the data comprises a value that is outside of a statistical control limit. Therefore, it is Applicants’ position that Sheehan does not teach or suggest a data acquisition mechanism, as recited in claim 8, and that Frasca does not provide the missing disclosure. Additionally, claim 8 recites, *inter alia*, a data analysis mechanism being adapted to generate information that includes at least one level of intervention when the data obtained from

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an individual comprises a value that is outside of a control limit and that the information is displayed to the individual. Applicants are unable to find any such teaching or suggestion in Sheehan or Frasca. Therefore, Applicants submit that the combination of Sheehan and Frasca does not teach or suggest each and every element of claim 8.

The Office Action states that Sheehan does not disclose at least one data analysis mechanism . . . wherein the data analysis mechanism performs at least one analysis selected from the group of population comparison” (The Office Action, page 2, bottom – page 3, top). The Office Action cites Frasca at col. 13, lines 58 – col. 14, line 6 to provide the missing disclosure of Sheehan. The Office Action states “it would have been obvious for one of ordinary skill in the art to have modified the teachings of Sheehan with the aforementioned teachings from Frasca . . . if a parameter falls outside a clinical (i.e., population comparison) range as recited in Frasca Jr. (col. 3, lines 21 – 26).” (The Office Action, page 3). Looking to the cited portion of Frasca, Applicants respectfully disagree with the Office’s reading of Frasca.

As best understood by Applicants, the cited portion of Frasca discloses that a value in a data record may be compared to a “clinical range” to determine whether the value (*i.e.*, the patient) should be processed further or receive some sort of additional attention. (Frasca, col. 3, lines 21 – 26). However, Applicants would like to point out that there is no teaching or suggestion in Frasca that the clinical range is generated from population data or that such a comparison amounts to a population comparison, as is recited in the present application. Applicants submit that one of ordinary skill in the art would appreciate that a population comparison generally requires a comparison of one individual to a population of at least one other individual, and that a population may include hundreds or even thousands of individuals. Applicants further submit that Frasca does not teach or suggest that the clinical ranges of Frasca are provided by even one other individual. Thus, Applicants submit that there is no teaching or suggestion of a population comparison, as asserted in the Office Action.

With regard to claim 7, Applicants are unable to find any disclosure of a data acquisition mechanism including a PDA (*i.e.*, personal digital assistant) or handheld computer in the cited portions of Sheehan. The Office Action cites Sheehan at Figures 3 – 5 and at col. 8, lines 18 – 32 for such disclosure. As best understood by Applicants, col. 8, lines 18 – 32 of Sheehan describe a base unit for receiving and holding the otoscope of Sheehan. Figures 3 – 5 of Sheehan

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show the otoscope of Sheehan, while Figure 8 shows the base unit. It is Applicants' position that the base unit of Sheehan is not a PDA or handheld computer, as is recited in claim 7 of the present application. Applicants note that the Office Action also cites to Frasca for support in rejecting claim 7, but that the Office Action does not point to any particular portion of Frasca for the relevant disclosure. (The Office Action, page 4). Applicants respectfully remind the Office that an Office Action must point out the particular portion of Frasca relied upon to support the rejection as nearly as practicable. (See, 37 CFR 1.104(c)(2)). Therefore, absent any evidence to the contrary, Applicants submit that the combination of Sheehan and Frasca does not teach or suggest each and every element of claim 7.

In light of the forgoing remarks, it is Applicants position that the Office Action has not made a *prima facie* case of obviousness with regard to independent claims 1, 6, 8 and 9 or any claim depending therefrom. Accordingly, Applicants respectfully request that the rejection of claims 1 – 10 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

Rejection Under 35 USC §103(a) Over Sheehan in view of Frasca and Ekblad

Claim 3 has been rejected under 35 U.S.C. 103(a) over Sheehan in view of Frasca and U.S. Pat. No. 5,920,478 to Ekblad, *et al.*, (hereinafter "Ekblad"). Applicants respectfully traverse the rejection.

The Office Action states "Sheehan does not teach that the at least one data analysis mechanism further comprises automatic or triggered recalculation of control limits based on top demonstrated historical performances." (The Office Action, page 7, bottom). The Office Action looks to Ekblad for the missing disclosure. Even assuming, *arguendo*, that Ekblad contains the disclosure for which it is cited, Ekblad still does not overcome the lack of teaching or suggestion mentioned above with regard to claim 1. Thus, there can be no teaching or suggestion of each and every element of claim 3 of the present application, which depends from claim 1. Accordingly, Applicants respectfully request that rejection of claim 3 under 35 U.S.C. 103(a) over Sheehan in view of Frasca and Ekblad be reconsidered and withdrawn.

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Rejection Under 35 USC §103(a) Over Sheehan in view of Frasca and Loman

Claim 4 has been rejected under 35 U.S.C. 103(a) over Sheehan in view of Frasca and U.S. Pat. No. 6,642,592 issued to Loman, *et al.*, (hereinafter "Loman"). Applicants respectfully traverse the rejection.

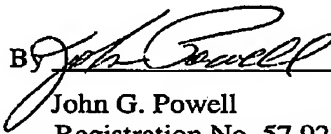
The Office Action states "Sheehan does not teach that the reliability engineering analysis includes time between failures and failure duration." (The Office Action, page 8, middle). The Office Action cites Loman to overcome the failings of Sheehan. However, even assuming, *arguendo*, that Loman contains the disclosure for which it is cited, Loman does not overcome the failings of Sheehan and Frasca described above. Accordingly, Applicants respectfully request that the rejection of claim 4 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

Conclusion

This amendment represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. Applicants respectfully requests that the rejection of the claims be reconsidered in light of the claim amendments and arguments set forth herein and that claims 1 – 10 be allowed.

Respectfully submitted,

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